K002180

OCT 1 3 2000

Sterling Medivations, Inc.
180 Ferndale Road South
Wayzata, Minnesota 55391
952-473-7971 (voice)
952-473-4758 (fax

510(k) SUMMARY
510(k) Number: K002180 Simplicity™ Disposable Pen Needle
(Hydrodermic Single Lumen Needle, Insulin Syringe)

Date Submitted: August 1, 2000

Submitter: Sterling Medivations, Inc. 180 Ferndale Road South, Wayzata, MN 55391
Company Phone 952-473-7971, Company Fax 952-473-4758

Contact: Joel Douglas, Chief Technology Officer
Sterling Medivations, Inc.
Applicant Phone 650-949-0470, Applicant Fax 650-949-0342

Trade Name of Device: Simplicity™ Disposable Pen Needle 510(k) Number: K002180
For Use with the InjectRite-C15 and InjectRite-C30™
Common Name of Device: Insulin Pen Needle
Classification Name: Hydrodermic Single Lumen Needle, Insulin Syringe

Predicate Device: Novo Nordisk NovoFine® 30 single-use disposable needles (K861686)

Decription of the New Device: Sterling Medivation Inc.'s ("SMI") Simplicity™ single-use disposable pen needles are sterile, non-pyrogenic single-use disposable pen needles designed to be used with the SMI InjectRite-C products, that are sold separately, which are designed for use by and for diabetics for the subcutaneous injection of a desired dose of insulin. The Simplicity will be offered with a 29 and 30 gauge needle both 8mm long.

The Simplicity™ single-use disposable pen needle is similar to the Novo Nordisk NovoFine® 30 single-use disposable needles (K861686). The SMI Simplicity™ pen needle is comprised of a siliconized stainless steel cannula welded into a polypropylene hub. A polyethylene protective inner shield snaps onto the hub over the needle. This assembly fits into a polypropylene outer protective container, the outer shield, which provides a sterile barrier along with a peel tab for access.

The SMI Simplicity™ pen needle does not have a threaded hub, a feature that differs from currently available pen needles. The InjectRite-C system uses a needle adapter to lock the needle in place. This provides the positive benefit of not having to siliconize the portion of the needle that punctures the rubber septum on the insulin cartridge (sold by others). This eliminates a contamination mechanism for the insulin contained in the cartridge.

When the injection is needed, the peel tab and outer protective shield are removed and the needle is inserted in the SMI InjectRite-C needle adapter and the needle adapter is twist locked onto the cartridge adapter. The inner shield remains on the needle until the insulin is ready to be injected.

When the injection is needed, the inner shield is removed and the needle is inserted into the chosen site. The InjectRite-C delivers the insulin from the insulin cartridge through the needle. The inner shield is replaced and the needle removed from the needle adapter, placed back in the outer shield and disposed of properly.

Intended Use of the New Device: The intended use of the SMI Simplicity single-use disposable pen needle is designed for use by and for diabetics for the subcutaneous injection of a desired dose of insulin. This is identical to the use of the predicate device, Novo Nordisk NovoFine® 30 single-use disposable needles (K861686).

Comparison of the Technological Features of the New Device and Predicate Device:

SMI Simplicity™ single-use disposable pen needle proposed for commercial distribution is similar in all significant respects to the existing Novo Nordisk NovoFine 30 Pen Needle.

The materials and manufacturing processes are substantially equivalent The labeling is substantially equivalent to the Novo Nordisk NovoFine® 30 single-use disposable needles (K861686) and the intended use is identical.

The differences that exist between the new and predicate device are as follows:

1.) The needle length on the new device will be offered with a 29 and 30 gauge needle. The predicate device is offered with a 30 gauge needle.
2.) The needle tip configuration complies with ISO standard ISO 7864: 1993 Sterile hypodermic needles for single use. The predicate device is a 45 degree single bevel needle tip.
3.) The Simplicity pen needle does not have a threaded hub a feature that differs from currently available pen needles.

These modifications do not affect the safety or effectiveness of the device.

Performance Data Supporting Substantial Equivalence: To prove substantial equivalence between SMI Simplicity™ single-use disposable pen needle and the Novo Nordisk NovoFine 30 Pen Needle K861686 the requirements of the proposed ISO/FDIS 11608-2 were used. Sterling Medivations, Inc. certifies that the SMI Simplicity™ single-use disposable pen needle meets the requirements of the proposed ISO standard ISO/FDIS 11608-2, Pen-injectors for medical use – Part 2: Needles- Requirements and test methods, the AAMI Radiation Standard, the needle conforms to the ISO 9626 Stainless steel needle tubing for the manufacture of medical devices, ISO 7864 Sterile hypodermic needles for single use, ISO 7886-1 Sterile hypodermic syringes for single use – Part 1: Syringes for manual use and CDHR 21 C.F.R. section 801.403 INSULIN SYRINGES and the design process adhered to is the Center for Devices and Radiological Health. DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS. This Guidance relates to FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001. This is substantially equivalent to the predicate device.

Signed,

Joel S. Douglas
Chief Technology Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2000

Mr. Joel S. Douglas
Chief Technology Officer
Sterling Medivations, Incorporated
180 Ferndale Road South
Wayzata, Minnesota 55391

Re: K002180
Trade Name: Simplicity Disposable Pen Needle
Regulatory Class: II
Product Code: FMI
Dated: July 17, 2000
Received: July 19, 2000

Dear Mr. Douglas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002180

Indications for Use enclosure

The intended use of the SMI Simplicity single-use disposable pen needle is designed for use by and for diabetics for the subcutaneous injection of a desired dose of insulin. Which is identical to the use of the predicate device the Novo Nordisk NovoFine® 30 single-use disposable needles (K861686) marketed by Novo Nordisk Pharmaceuticals Inc., of Princeton, NJ 08540.

Brenda Belden

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002180